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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/19/2000

Mark H. Theno

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08/09/2004

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EXAMINER

YU, GINA C

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/691,896	THENO, MARK H.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-14,17-31 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-14, 17-31, 40, 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of Amendment filed on March 8, 2004. Claims 1, 3-8, 10-14, 17-31, 38-41 are pending. Claims 38-39 are withdrawn from consideration. Claim rejections made under 35 U.S.C. § 112, second paragraph as indicated in the previous Office action dated July 7, 2003 are withdrawn in part and maintained in part. Claim rejection made under 35 U.S.C. § 103 (a) over Cartmell et al. (US 5501661) in view of Fischel-Ghodsian (US 5455043) is withdrawn and modified to meet the new claim limitation. Claim rejection made under 35 U.S.C. § 103 (a) over Cartmell et al. and Fischel-Ghodsian and further in view of Wick et al. (US 6010715) is maintained for the reasons of record.

Election/Restrictions

Claims 38 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. While applicants state in reply that the election is made with reservation to traverse, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is vague and indefinite because the claim recites that the "open cell foam" may be a same or different material from the polyolefin which is already used in the foam pad in claim 40. Claim 40 recites that the foam pad comprises a foamed polyolefin; claim 24 recites that the foam can be either synthetic or natural open cell foam; and claim 41 further defines that the open cell foam can be polyolefin, acrylic adhesive, or hydrogels. The confusion arises as to whether the "open cell foam" is different from the said foam in claim 40.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-8, 10-12, 17-20, 23-27, 29-30, 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. (US 5501661) ("Cartmell") in view of Fischel-Ghodsian (US 5455043).

Cartmell teaches a wound dressing product containing a porous layer. The wound dressing product comprises an optional release liner, an optional removable tab, and a wound dressing. The wound dressing comprises a thin-film layer, an adhesive layer, a porous backing layer, an optional support layer and a hydrogel material. The thin-film layer has a first side and an opposing second side and forms the outer surface of the dressing product. The adhesive layer is positioned on the second side of the thin-

film layer. The backing layer is constructed of a porous material comprising a polyolefin foam. The porous backing layer has a first side and an opposing second side, and is adhered to the second side of the thin-film layer by the adhesive layer. The optional support layer is made from a material such as woven and nonwoven fabrics. The hydrogel material may be secured to the second side of the support layer. The permeable fabric of the support layer allows the hydrogel material to pass through to the first side of the support layer. The optional release liner overlies the hydrogel material and is secured to the perimeter portion of the second side of thin-film layer by means of the adhesive layer. The optional removable tab is interposed between the thin-film layer and the release liner. The porous layer is taught as having open spaces, thereby giving the layer its porosity. The Cartmell reference clearly teaches that the invention is designed to permeate vapor "which permits the transpiration of moisture through the wound dressing". Thus, as indicated in the previous Office action, the reference clearly teaches that a skilled artisan would have expected that the invention is used to transport vapors.

While the reference does not explicitly states that vapor emitting materials are stored within the foams, examiner respectfully points out that it is implicit in the teachings of Cartnell et al., as the foam layer is the layer though which oxygen and other vapor-permeable substances are transferred from the wound to the environment. The reference teaches that the structure of the patch as claimed is well known in the art, except that the reference is silent as to the cellular structure of the foam. The reference fails to teach that a vapor emitting material is stored in the patch "prior to use".

Fischel-Ghodsan teaches that patches comprising polyolefin foams, such as polyolefin foams, such as polypropylene foams and polyethylene foams. The reference teaches that varying the porosity of the cellular structure of the foam is within the skill of the art. See col. 5, lines 14-25. The reference teaches that vapor emitting compounds such as therapeutic agents are incorporated in the reservoir layer of the patch. See col. 6, line 56 – col. 7, line 7. See instant claim 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modified the polyolefin foams of Cartmell et al. as having a cellular structure as taught by Fischel-Ghodsan because the latter teaches polyolefin foams as having cellular structures as part of their form because of the expectation of achieving a foam form that matches the rate of emission with the porosity of the cell sizes. Incorporation of vapor emitting compounds in the foams of Cartmell is viewed an obvious variation of the prior art in view of Fischel-Ghodsan because the skilled artisan would have been motivated to successfully produce a therapeutic medication.

Claims 13, 14, 21, 22, 28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell in view of Fischel-Ghodsian as applied to claims 1, 3-8, 10-12, 17-20, 23-27, 29, 30, 40, 41 as above, and further in view of Wick et al. (US 6010715) ("Wick").

Cartmell and Fischel-Ghodsian are applied as discussed above. The references lack a teaching of the release layer being made of polyolefin, polyamide, cellulosic, or polyethylene terephthalate.

Wick teaches a transdermal patches. The backing layer is taught as being made of cellulose acetate, ethyl cellulose, polyethylene terephthalate and others. These compounds are taught as being made of a material that is substantially impermeable to the layer or layers with which it can be in contact. The patches are taught as being kept sealed in an air-tight pouch prior to use. See col. 14, lines 34-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the release liner of Cartmell et al. as being made of cellulose acetate, ethyl cellulose, or polyethylene terephthalate, as taught by Wick because of the expectation of achieving a product that is impermeable to the hydrogel, thereby keeping the product intact.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the patches of the combined references as being kept sealed in an air-tight pouch prior to use, and thereby having to remove the patch from the seal for use, as taught by Wick, because of the expectation of achieving a patch that is sterile.

Response to Arguments

Applicant's arguments filed March 8, 2004 have been fully considered but they are not persuasive.

Applicant's argument that the Cartmell reference teaches away from the presently claimed invention is unpersuasive. Applicant further asserts that oxygen is not vapor but a gas. The argument is not persuasive because the reference clearly

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indicates that the prior art invention is designed to permit the transport of moisture vapor.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

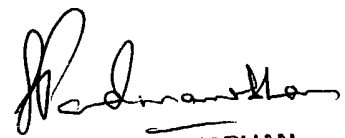
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina C. Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER